

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



Participants:

- | | |
|---|----------|
| 1. Prof. Dr. Nasir Chaudhary
Head of Ophthalmology Department Unit-II Mayo Hospital Lahore | Chairman |
| 2. Dr. Umar Nazir
Assistant Professor of Plastic Surgery Mayo Hospital Lahore | Member |
| 3. Dr. Sana Farooq
Senior Registrar Neurology Department Mayo Hospital Lahore | Member |
| 4. Mr. Azeem Butt
Deputy Drugs Controller Mayo Hospital Lahore | Member |
| 5. Mr. Muhammad Jawad Bhatti
Deputy Drugs Controller Mayo Hospital Lahore | Member |

Proceedings:

Meeting started with the recitation from the Holy Quran. The Chairman, Grievances Committee Mayo Hospital Lahore welcomed all the participants.

ITEM NO. 01: GRIEVANCE SUBMITTED BY M/S BAJWA PHARMACEUTICALS(TENDER: A01DRUGS/ MEDICINES)

GRIEVANCE DETAIL: The firm submitted the grievance that due to some documents error, the firm has been given low marking in some of quoted items. The firm stated that it is providing the required documents to meet the need of procurement procedure for T.E 6, 7, 44 & 48. The firm claimed to provide documents pertaining to API, Experience/ Pos, Primary Reference Standards & Invoices.

Decision: Mr. Azeem Khan Institutional Manager of M/S Bajwa Pharmaceuticals (Pvt.) Ltd. pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for TE No. 6, 7, 44 and 48 due to failure in marking criteria and for TE No. 186 as not per Specs. The committee also observed that the firm has not attached enclosures with the grievance letter.

The firm's representative claimed 10 marks for T.E. 06 in clause (4) of Ordinary Parameters. He showed PO No. 9901-04/SZH dated 11.08.22 & Delivery Challan No. 95 dated 29.08.22 to supply 65000 of Inj. Atracurium

Office of Chairman Grievances Committee, Mayo Hospital Lahore
18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



Besylate to Sheikh Zayed Hospital Rahim yar Khan; PO No. K02240000464 dated 25.03.24 & Delivery Challan No. 822 dated 30.03.24 to supply 25000 injections of instant drug to Lady reading Hospital Peshawar; and PO No. 81775 dated 05.12.23 & Delivery Challan No. 938 dated 29.02.24 to supply 40000 injections to Mayo Hospital Lahore. The committee awarded 10 marks in clause (4) of Ordinary Parameters, and declared responsive in ordinary Parameters by attaining 51 marks.

The firm's representative then claimed 7 marks for T.E. 07 in clause (4) of Ordinary Parameters. He showed PO No. 11691 dated 10.10.23 & Delivery Challan No. 932 Dated 05.03.24 to supply 5000 injections of Atracurium Besylate 5ml to Aziz Bhatti Shaheed teaching Hospital Gujrat, however the marks remained same. Due to which the TEC decision remains unchanged to this extent.

The firm's representative claimed further marks for T.E. 48 and provided PO No. 79503/MH dated 19.11.2022 & DC No. 201 dated 18.01.2023 to supply 10,000 injections of said drug. The firm further showed PO No. K02230002027 dated 20.09.2023 to supply 10000 injections but the date of PO mentioned on DC No. 590 dated 28.09.2023 was different i.e. 20.08.24. The firm then showed PO issued from DGHS KPK to supply 60000 injections but the document did not contain PO No and complete date. The committee regretted the grievance for T.E. 48. The firm also did not present any supportive document for T.E. 44 for which the TEC decision remained unchanged.

ITEM NO. 02:

GRIEVANCE SUBMITTED BY M/S ROCHE PAKISTAN (TENDER: A01 DRUGS/ MEDICINES)

GRIEVANCE DETAIL:

The firm submitted the grievance regarding the qualification of product Trastuget 440 mg, which Getz Pharma is importing from Biocon, India which has been technically approved in the evaluation report against bid inquiry no. 148. The firm stated that as per the compulsory parameters specified in the tender documents, Clause XI which states that the bidder is required to

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

Page 2 of 19

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



provide biosimilarity study data for the quoted item (applicable to biologicals and biotech products). The biosimilar study must be conducted by labs notified by DRAP or accredited by WHO/JpMHLW/EMA/US FDA. Alternatively, the quoted product must have the status of reference product for biosimilar studies by the US FDA/ registered at EMA official website. The firm added that upon review, the biosimilarity study referenced in Getz Pharma's marketing materials pertains to the Heritage Trial Phase III, sponsored by Mylan GmbH for their brand—not specifically for Trastuget as claimed. This raises concerns about the accuracy and compliance of the submitted data (attached is documentation of the trial, clearly identifying Mylan GmbH as the responsible entity and funder of the study) through Clinical trial identification: EudraCT No: 2011-001965-42, Legal entity responsible for the study is Mylan GmbH through Funding by Mylan GmbH

The firm then stated that the clause X of the compulsory parameter states that Quoted product must have WHO Prequalification /JpMHLW / EMA / USFDA approval. Contrary to the claims made, publicly available information from the official websites of these regulatory bodies indicates that Trastuget 440 mg by Getz Pharma does not feature in the lists of approved biosimilars:

FDA Biosimilar Trastuzumab 440 mg:

<https://purplebooksearch.fda.gov/results?query=trastuzumab&title=Herceptin>

EMA Biosimilar Trastuzumab 440 mg:

https://www.ema.europa.eu/en/search?search_api_fulltext=trastuzumab&f%5B0%5D=ema_search_topics%3A45

WHO Prequalified Trastuzumab 440

mg:<https://extranet.who.int/prequal/news/first-biosimilar-product-prequalified>

Office of Chairman Grievances Committee, Mayo Hospital Lahore
18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



The firm claimed that it is evident that Trastuget 440 mg by Getz Pharma fails to satisfy the mandatory requirements specified in Clauses X and XI of the tender documents.

Decision:

Mr. Shabbir Khan Commercial Manager of M/S Roche Pakistan pleaded the case before the grievances committee. Mr. Imran Answer Senior Sales Manager defended the grievance on behalf of M/S Getz Pharma. The petitioner presented the above-mentioned grievance. The defendant stated that the heritage Trail is co-sponsored by M/S Biocon Biologics India &M/S Mylan India and presented a reference of FDA. The defendant further stated that the biosimilar studies are conducted to demonstrate that generic drug is bioequivalent to brand-name drug. He further stated that M/S Biocon Biologics India produces finished product Trastuzumab and offers to different countries with different brand names and presented a Certificate of Pharmaceutical Product issued from Government of Karnataka to support its claim. In lieu of above facts the committee observed that the product manufactured by M/S Biocon Biologics is biosimilar and upheld the decision of Technical Evaluation Committee in clause (xi) of Compulsory Parameters. The defendant further stated that its product also qualifies the requirements of clause (xii) of Compulsory Parameters and has been qualified by the Technical Evaluation Committee. He stated that WHO has granted prequalification status to Trastuzumab 420mg &440mg manufactured at M/S Biocon Biologics through No. BT-ON017&BT-ON014. He further stated that Trade names are not prequalified by WHO and proprietary names given as example only. WHO prequalifies the Finished Pharmaceutical Product irrespective of trade names. The defendant further claimed that its offered product is WHO approved. The committee decided to uphold the decision of Technical Evaluation Committee in this respect as well.

ITEM NO. 03:

GRIEVANCE SUBMITTED BY M/S SAMI PHARMACEUTICALS(TENDER: A01 DRUGS/ MEDICINES)

GRIEVANCE DETAIL:

The firm submitted the grievance with reference to an inadvertent error in S.No of its quoted product whereas Sr. No. 67 has been mentioned

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



inadvertently instead of 122 for Inj. Filgrastim 0.3mg. The firm has submitted revised Technical Bid Form 8.3 for the product quoted with correct S.No.

Decision:

Mr. Abid Ali National Sales Manager of M/S SamiPharmaceuticals (Pvt.) Ltd. pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for TE No. 122 in Compulsory parameters and marking criteria. The firm's representative stated that the firm inadvertently mentioned T.E. No. 67 instead of T.E. No.122 due to typographical mistake, however the exact name of Inj. Filgrastim 0.3mg has been mentioned as per nomenclature mentioned in advertised bidding document. The committee observed that the firm has also been disqualified in Ordinary Parameters due to less marks, for which the firm has not challenged the TEC Report. The committee decided to uphold the decision of Technical Evaluation Committee.

ITEM NO. 04:

GRIEVANCE SUBMITTED BY M/S A.J. MIRZA PHARMA(TENDER: A01 DRUGS/ MEDICINES)

GRIEVANCE DETAIL:

The firm submitted the grievance that it participated against inj. Surfactant (Bles 3ml), Inj. Oxaliplatin 50mg & 100mg (inj. Oxaliplatin 50mg & 100mg) and have been disqualified in compulsory criteria. Regarding Valid Sole Agency agreement: Clause vii, The firm stated that previously, it submitted an agency authorization by mistake, but has attached the sole agency agreement for evaluation. Regarding Biosimilar Studies: Clause xi, The firm stated that it has quoted Inj Bles 3ml against T.E # 160 Inj. Lung Surfactant, that is an innovator product which biosimilar studies did not exist. The firm imports Bles inj. from Canadian company BLES BIOCHEMICAL INC. Bles is fast acting Lung Surfactant derived from minimally invasive lavage process. The firm also claimed to attach monograph for detailed study of product.

Against M/S Pharmasol:

The petitioner stated that M/S Pharmasol's products does not meet the requirement of having one year of experience with the quoted product (T.E

Office of Chairman Grievances Committee, Mayo Hospital Lahore
18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



133 & 134) at the time of tender submission and requested to review whether defendant products meet the compulsory parameter #ix.

Against M/S Himmel Pharma:

The petitioner stated that defendant does not meet compulsory clause # x for quoted product regarding meeting criteria to be WHO prequalified/JPHMLW/EMA/USFDA approved for T.E # 133 & 134 products.

Decision:

Ms. Maryam Khan Senior Specialty Manager and Mr. Muhammad Saeed Sales Manager of M/S A.J. Mirza Pharma (Pvt.) Ltd. pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for all quoted items due to failure in clause vii of compulsory parameters. The firm claimed that it has attached Letter of authorization in the bid. And has provided Sole Agency Certificate between M/S Bless Biochemicals Inc and M/S A.J. Mirza Pharma (Pvt.) Ltd. established on 2018. The firm also provided Sole Agency Agreement between Jiangsu Henguri Medicine China and M/S A.J. Mirza Pharma (Pvt.) Ltd established on 2019. The committee decided to declare firm responsive in clause Vii of Compulsory Parameters. The firm further stated that its quoted product T.E. 160 is an innovative/ research product and does not fall under Biosimilar product. The committee observed that the firm's representative failed to claim that the said brand has not been used as reference product for biosimilar studies on FDA & EMA official sites due to which T.E. 160 remained non-responsive. **T.E. 133 & 134 were declared responsive, however, T.E. 160 remained non-responsive.**

Grievance Against M/S Pharmasol

Mr. Malik Bahadur defended the grievance on behalf of M/S Pharmasol. The petitioner presented the grievance and requested to review firm's qualification to the extent of clause (ix) of Compulsory Parameters. The committee observed that T.E. 133 & 134 have been registered on 31.01.2023 and fulfills the requirements of Clause (ix) of compulsory

Office of Chairman Grievances Committee, Mayo Hospital Lahore
18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



parameters. The committee decided to turn down the grievance against M/S Pharmasol.

Grievance Against M/S Himmel Pharma


The petitioner withdrew the grievance against the said firm.

ITEM NO. 05:

GRIEVANCE SUBMITTED BY M/S G.T. PHARMA(TENDER: A01 DRUGS/ MEDICINES)

GRIEVANCE DETAIL:

The firm submitted the grievance that M/S English Pharma is unable to fulfill the obligations regarding timely supply on their part, which adversely effect the functionality of health facilities in institutions which will result in Local Purchase that adversely effect the hospital financially. The firm also pointed out some significant concerns regarding the efficacy of the product inj vitamin k quoted by English Pharma which is quoted against Sr no 227. The firm claimed that the technical evaluation report of Director General Health Service Punjab mentioned great concern regarding the efficacy of the products as there were no validation studies of MS specifications were provided, testing of pharmaceuticals was being performed on in-house methods but the label claim was USP specs. E.g. Escitalopram tablet and iron sucrose complex, all the equipment including atomic absorption, TOC, Karl fishcer, were calibrated by DAWN calibration laboratories recognized by PNAC. The log books of said equipment were not in place they were asked to provide but they were not provided. The DAWN Calibration lab is an accredited lab by the PNAC for seven parameters but they have calibrated all the equipment which are out of their scope. On inspection of chemicals, many of the chemicals were not having their opening date and expiry date, and few of the chemicals were found expired. No data of reagents standardization was available. The cleanliness of the lab was compromised. One of the two stability chamber was found under maintenance. The firm then claimed that the mandatory parameter of the products are compromised leading in to sub-standard declaration of the product from DTLs of Punjab over 5%. This declaration of substandard products will lead


Office of Chairman Grievances Committee, Mayo Hospital Lahore
18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



into the delay of patient treatment and loss of public money as well. The firm requested to review the quality of vitamin K injection of English Pharma to ensure that it meets the necessary standards for patients' treatment. Efficacy of the products so kindly remain English Pharma as non-responsive.

Decision:

Mr. Mr. Yasir Distributor of M/S G.T. Pharma (Pvt.) Ltd. pleaded the case before the grievances committee. The committee observed that the defendant was absent and was already disqualified from the instant tender.

ITEM NO. 06:

GRIEVANCE SUBMITTED BY M/S IPRAM PHARMACEUTICALS (TENDER: A01 DRUGS/ MEDICINES)

GRIEVANCE DETAIL:

The firm submitted the grievance that the Technical Evaluation Committee has given less marks in T.E # 11 due to product less experience in public sector.

The firm claimed that M/S IPRAM International is a GMP & ISO Certified Company and is also providing the same quoted products Imipenem + Cilastatin 500mg to most prestigious institutes of Pakistan including teaching Hospitals like Sir Ganga Ram Hospital Lahore, DHQ Teaching Hospital Sargodha, Jinnah Hospital Lahore, PIMS Islamabad, Holy Family Hospital Rawalpindi, BBH Rawalpindi and also marketing the same product for more than five years. The firm has claimed to attach Purchase order, award Letters and invoices for reference.

Decision:

Mr. Sheikh Nauman, Institutional Manager of M/S Ipram Pharmaceuticals (Pvt.) Ltd. pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for TE No. 11 due to failure in ordinary parameters by getting 41 marks. The firm's representative claimed more marks for T.E. 11 in clause (4) of ordinary parameters. The firm's representative showed PO No. 47759 dated 26.12.23 & DC No. 053 dated 12.02.24 to supply 10,000 injections to Jinnah Hospital Lahore; PO No. 49737/42 dated 26.10.23 & DC No. 8479 undated that was not accepted; PO No. 42904-7 dated 20.09.23 & DC No. 8462 dated 13.10.23 to supply 3500 injections to M/S Benazir Bhutto

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

Page 8 of 19

Yasir

John

M

MINUTES OF GRIEVANCES MEETING



MAYO HOSPITAL LAHORE

Hospital Rawalpindi; PO No. 1543 dated 25.09.23 & DC No. 202 dated 14.10.23 to supply 500 injections to M/S Institute of Kidney Diseases Hayatabad Peshawar; PO No. 2029-33 dated 16.09.23 & DC No. 8460 dated 06.10.23 to supply 3800 injections to M/S Holy Family Hospital Rawalpindi; PO No. 44165-70 dated 28.09.23 & DC No. 8476 undated that was not accepted; PO No. 891 dated 21.09.23 & DC No. 8473 undated that was also not accepted; PO No. 42795-800 dated 20.09.23 & DC No. 8478 undated that was not accepted; PO No. 37046-50 dated 01.08.22 & DC No. 7773 dated 20.09.22 where PO dated mentioned was 11.08.22, that was also not accepted due to disparity. The committee observed that the instant documents failed to enhance points already marked by the Technical Evaluation Committee. The firm's representative also claimed more marks in clause 11 of Ordinary Parameters but failed to provide sufficient documents that could enhance marks in instant case. The firm also presented an affidavit claiming 07 stability chambers but failed to provide validation/calibration data of these chambers. The committee upheld the decision of Technical Evaluation Committee.

ITEM NO. 07:

GRIEVANCE SUBMITTED BY M/S A.A. PHARMACEUTICALS(TENDER: A01 DRUGS/ MEDICINES)

GRIEVANCE DETAIL:

The firm submitted the grievance that the firm participated in tender for Inj. Erythropoeitin 4000IU PFS (EPIAO 4000IU), Inj. gemcitabine 200mg & 1000mg (Inj. Zefei 200mg & 1000mg) that have been disqualified. The firm stated that regarding Valid CNIC: Clause ii, the CNIC of the signatory was submitted by mistake and has now provided the correct CNIC of the authorized personnel. Regarding Valid Authorization: Clause iv, the firm has attached authorization from principal companies and has now attached authority letter of authorized person. Regarding Valid Sole Agency agreement: Clause vii, the firm stated that it submitted an agency authorization and has now attached the sole agency agreements for evaluation. The firm then referred to Ordinary Parameters and stated that regarding Experience in Public sector: Clause 3, the firm has been awarded

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



zero marks in this category due to the non-submission of Delivery Challans (DCs). Although purchase orders were attached. The firm has claimed to attach the required DCs for consideration.

Regarding availability in other countries: Clause 8: the firm has been awarded zero marks because firm initially submitted registration letters for 25 countries for EPIAO but lacked the necessary air waybills. The firm has claimed to provide the air waybills for both products.

Grievance against B.F Biosciences:

The petitioner stated that M/S B.F. Biosciences has been technically qualified for the compulsory parameter but there are concerns regarding their compliance with clause number xii of the compulsory criteria i.e. BIOSIMILAR STUDIES. The firm stated that it has doubt that they do not have any bio similar studies through WHO/ JPHMLW/EMA/ USFDA approved or accredited lab.

Decision:

Mr. Ms. Maryam Khan Senior Specialty Manager and Mr. Muhammad Saeed Sales Manager of M/S A.A. Pharmaceuticals (Pvt.) Ltd. pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for all quoted items due to failure in clauses ii, iv& vii of compulsory parameters and less marks in ordinary parameters for all quoted items. The firm's representative stated that the firm mistakenly attached the CNIC of Mr. Ali Abbas Inayatullah, proprietor of firm and provided copy of CNIC of Ms. Maryam Khan, the bid signatory. **The committee declared the bid responsive in clause ii of compulsory parameters.** The firm stated that it has attached the authorizations of firm from principals i.e. Shenyang Sunshine Pharmaceutical China and Jiangsu Hansoh Pharmaceutical China. However, the firm has also attached authority letter for the bidder. **The committee decided to declare firm responsive in clause iv of compulsory parameters.** The firm then showed an Tripartite Agreement between Shenyang Sunshine Pharmaceuticals, A.A. Pharma and A.J. Mirza Pharma where it has been

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



mentioned that the A.A. Pharma shall remain the exclusive distributor of EPIAO vial./prefilled syringe until the drug registration is transferred to A.J.Mirza Pharma. The firm's representative further stated that the A.A. Pharma still holds the drug registration of said drug. **The committee decided to declare firm responsive in clause vii of compulsory parameters.**

The firm provide PO No. INOR-ADM-RCD-277(2022-23 & 24 dated 03.04.23 & DC No. 26171 dated 17.04.23 to supply 1500 injections of T.E. 125&1000 injection of T.E. 124 to Institute of Nuclear Medicine Oncology & Radiology Abbottabad (INOR); PO No. INOR-ADM-RCD-277(2022-23 & 24 dated 20.11.23 to supply 700 injections of T.E. 125 and 450 injections of T.E. 124; PO No. 538 dated 27.09.23 & DC No. 27253 dated 28.09.23 to supply 100 injections each of T.E.. 125 & 124 to INMOL Patient Welfare Society Lahore; PO No. INOR-ADM-RCD-277(2022-23 & 24 dated 11.08.23 & DC No. 26943 dated 18.08.23 to supply 800 injections of T.E. 125 & 400 injections of T.E. 124 to INOR. The committee observed that the TEC has awarded zero marks in clause (3) of Ordinary Parameters. The committee awarded 07 marks in T.E. 125 and 5 marks to T.E. 124 in clause (3) of Ordinary parameters. **T.E. 124 & 125 stands responsive in Ordinary Parameters by achieving 48 and 50 marks respectively.** The firm also claimed more marks in clause (8) of T.E. 9. The firm stated that the principal doesn't provide Purchase Orders & Invoices of other countries due to confidentiality and contractual obligations with other institutions worldwide. However, the firm provided an Authorization Status issued by Shenyang Sunshine Pharmaceutical China where it has been mentioned that EPIAO has been registered in different countries including Egypt, Brazil, Thailand, Sri Lanka etc. The firm further provided Airway Bill No. 180-39771760 for shipment to Thailand. Airway Bill No. 057-50155781 for shipment to Brazil. Airway Bill No. 160-73808630 for shipment to Sri Lanka & Airway Bill No. 157-55213093 for shipment to Egypt. The committee decided to award 4 marks to T.E. 9 under section (8) of ordinary parameters. **The T.E. stands responsive by achieving 47 marks in Ordinary Parameters.**

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

Page 11 of 19

MINUTES OF GRIEVANCES MEETING



MAYO HOSPITAL LAHORE

Grievance against BF Biosciences

Mr. Asif National Institutional Manager defended the case on behalf of M/S BF Biosciences. The petitioner claimed that BF Biosciences T.E. 8 & T.E. 9 does not qualify the requirements of clause xii as the firm does not have biosimilar studies from WHO/JPHMLW/EMA/USFDA approved/ accredited labs. The firm's representative stated that it has attached in-house biosimilar study in the bid conducted by BF Biosciences that is not accredited by these authorities. The firm then provide biosimilar studies documents conducted by Gemabiotech Argentina that has marketing authorization for certain finished dosage forms and Zelltek S.A is an API manufacturing company from where BF Biosciences is also importing. The firm also admitted that in this study the Investigation Site Instituto de Nefrologia Pergamino S.R.L. Argentina is not approved/ accredited by WHO/JPHMLW/EMA/USFDA. **The committee accepted the grievance and declared T.E. 8 & T.E. 9 offered by M/S BF Biosciences disqualified in clause xii of Compulsory Parameters.**

ITEM NO. 08:

GRIEVANCE SUBMITTED BY M/S B.F. BIOSCIENCES(TENDER: A01 DRUGS/ MEDICINES)

GRIEVANCE DETAIL:

The firm submitted the grievance on technical evaluation report that Noxane (Inj Enoxaparin) 40mg & 60mg Prefilled Syringe has been disqualified on the ground of "non-provision of Accredited Lab Bio Similarity studies data/report," as stipulated in Clause VIII of the tender requirements. The firm stated that Clause xii mandates the submission of Bio Similarity Studies data, specifying that: "The bidder must submit bio similarity studies data of quoted item (for biologicals and biotech products). The biosimilar study must be from DRAP notified labs or WHO/JpMHLW/EMA/USFDA approved / accredited labs only OR quoted product must have status of reference product for biosimilar studies on US-FDA/registered at EMA official websites." The firm alleged that this particular clause disproportionately favors a single bidder, thereby disadvantaging numerous other prospective bidders, including BF Biosciences Limited. It further claimed that this

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



situation could compel hospital to rely on a single bidder, resulting in significantly higher procurement costs. The firm raised following points:

- 1) **Absence of Local Facilities to Conduct Bio Similarity Studies:** Currently, there are no testing laboratories within the country whether DRAP-notified or accredited by international agencies have the capability to conduct biosimilar studies. Consequently, bidders would be compelled to conduct these studies abroad, incurring significant cost and time, and expending valuable foreign exchange.
- 2) **Impact on Hospitals' Budget and Quality Concerns:** In the event that no bidder qualifies, the hospital would need to resort to local purchase at higher prices. Additionally, prequalifying a single bidder would force the hospital to pay up to 200% higher prices unnecessarily for the imported brand. These financial burdens could strain already limited budgets. Furthermore, high prices do not necessarily correlate with better quality. For instance, brand of Noxane has been used satisfactorily for many years by prestigious government institutions including Mayo Hospital for last two years without any issues related to clinical efficacy or desired outcomes.
- 3) **Shortage of Imported Medicine:** Over the past year, there has been a shortage of imported medicines. This scarcity has caused hospitals to incur financial losses, ultimately affecting poor patients who rely on these critical medications.
- 4) **Compliance with PPRA Act 2009:** The firm referred to following clauses PPRA Act:
 - a. **Clause 10(1) Specifications:** A procuring agency shall determine specifications in a manner to allow the widest possible competition which shall not favor any single contractor nor put others at a disadvantage.
 - b. **Clause 26(2) Reservations and Preference:** A procuring agency shall allow for a preference to domestic or national contractor in accordance with the policies of the Government and the magnitude

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

Page 13 of 19

MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE



of price preference to be accorded shall be clearly mentioned in the bidding documents under the bid evaluation criteria.

- c. Clause 34 Discriminatory and Difficult Conditions: Save as otherwise provided, no procuring agency shall introduce any condition, which discriminates between bidders or which is difficult to meet.

In light of the foregoing, and with utmost respect for the principles of fairness and competition, the firm requested a thorough review of "Clause VIII" as it pertains to "Noxane (Inj. Enoxaparin) 40mg & 60mg Prefilled Syringe (T.E No. 161 & 162)". The firm proposed that this clause be reconsidered and temporarily suspended until the requisite infrastructure for conducting Bio Similarity Studies is established within the country. Alternatively, the firm also suggested that this clause be moved from the compulsory to the ordinary parameters to ensure equitable opportunities and open competition for all bidders.

Decision:

Mr. Asif, National Institutional Manager of M/S B.F. Biosciences pleaded the above stated case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid in clause xii for TE No. 161 & T.E. 162. The firm's representative admitted that the firm does not have biosimilar studies from WHO/JPHMLW/EMA/USFDA accredited/ approved labs. The committee decided to regret the grievance and upheld the decision of Technical Evaluation Committee.

ITEM NO. 09:

GRIEVANCE SUBMITTED BY M/S GALLOP WATER SCIENCES(TENDER: A01 DRUGS/ MEDICINES)

GRIEVANCE DETAIL:

The firm submitted the grievance with reference to Technical Evaluation for purchase of Medicine/Drugs A-01 Financial Year 2024-25. The firm stated that it quoted Inj. GEE-Ligno 10ml against T.E No.44, Lignocain HCl 2% ,Ampule of 10ml, Bid Reference No 19.The product was declared "Non-Responsive". Inj. GEE-Ligno 10ml is given lesser marks in different parameters.Sr. No. 3 (A)Experience of quoted product last two year in

Law *Am*

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

[Signature]

MINUTES OF GRIEVANCES MEETING



MAYO HOSPITAL LAHORE

Private sector: Inj. GEE-Ligno 10ml has experience of private sector of advertised quantity. The firm admitted that due to Covid and consequent problems and limitations in import it could not procure raw material and had lesser experience in private sector. The firm requested to consider the unavoidable situation and give 10 marks. Regarding Sr. No. 4 (A) Experience of quoted product last two year in Govt. sector: Inj. GEE-Ligno 10ml has no experience of public sector hospitals of advertised quantity during last two years. The firm admitted that due to Covid and consequent problems and limitation in import it could not procure raw material and did not participated in public sector tenders. However in 2021-22 the firm has claimed to supply ampoules in public sector hospitals in previous years. The firm requested to consider the unavoidable past situation and give 10 marks as total in this parameter. Regarding Sr. No. 5 (D)Credibility and Certification of Manufacturer: For water treatment plant the firm has claimed to have SOPs and required facility according to requirement; however operation is responsibility of third party under contract and the firm requested to give 3 marks. Regarding Sr. No. 9 Primary reference standards: The firm has claimed to have complete primary reference standards for which copies of relevant documents are attached and the firm requested to give 2 marks. regarding Sr. No. 10 Technical Staff of Manufacturing Unit: (A) 10 Pharmacists are required in a manufacturing unit having different sections like solid dosage, liquid dose, parental, topical preparations, cephalosporin, hormones etc. The firm claimed that M/S Gallop Water Sciences is a parental plant and 4 pharmacists are appointed who supervise the processes skillfully and requested to give 2 marks.(B) The firm claimed to have 3 M.Phil personals and requested to give 2 marks. Regarding Sr. No. 11 (A)Availability of products at Major Chain pharmacies: The firm stated that GEE-Ligno is indicated for local anesthesia to hospitalized patients. It is a specialized hospital item and should be exempted from this requirement and requested to give 5 marks. The firm requested to accept its grievances to give 54 marks and declare Inj. GEE-Ligno 10ml as "Responsive".

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

Page 15 of 19

MINUTES OF GRIEVANCES MEETING



MAYO HOSPITAL LAHORE

The firm then referred to Technical Evaluation of tender (Bid Ref NO 19) where the firm quoted Inf. GEE Sol 25% 25ml against T.E No. 37, Inj. 25% Dextrose Water (Ampoule of 25ml). The product mentioned above was declared "Non-Responsive" due to lesser marks in different parameters. Sr. No. 4 (A) Experience of quoted product last two year in Govt. sector: The firm claimed that GEE Sol 25% 25ml has 154% experience of public sector hospitals of advertised quantity during last two years and requested to give 10 marks. Regarding Sr. No. 5 (D) Credibility and Certification of Manufacturer: The firm stated that for water treatment plant it has SOPs and required facility according to requirement. However, operation is responsibility of third party under contract and requested to give 3 marks. Regarding Sr. No. 9 Primary reference standards: The firm claimed to have complete primary reference standards for which copies of relevant documents are attached to gain 2 marks. Regarding Sr. No. 10 Technical Staff of Manufacturing Unit: (A) 10 Pharmacists are requirement with a manufacturing unit having different section like solid dosage, liquid dose, parental, topical preparations, cephalosporin, hormones etc. The firm's representative claimed that M/S Gallop Water Sciences is a parental plant and 4 pharmacists are appointed who supervise the processes skillfully, and requested 2 marks. (B) the firm claimed to have 3 M.Phil personals and requested 2 marks. Regarding Sr. No. 11 (A) Availability of products at Major Chain pharmacies: The firm submitted that Inj. 25% Dextrose is indicated for Hypoglycemic crises and patients are admitted in hospitals and ICU, so it is a specialized hospital item and should be exempted from this requirement. The firm requested to accept its grievances to give 51 marks and declare GEE Sol 25% 25ml as "Responsive".

Thirdly, the firm stated that it quoted Inf. GEE-Sol RL 500ml against T.E No. 36, Inf. Ringer Lactate 500ml (Bid Ref NO 19) which was declared "Non-Responsive" due to lesser marks in some parameters. Regarding Sr. No. 4 (A) Experience of quoted product last two year in Govt. sector: The firm claimed that GEE-Sol RL500ml has ample experience of public sector

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

Page 16 of 19

low *Am*

MINUTES OF GRIEVANCES MEETING



MAYO HOSPITAL LAHORE

hospitals of advertised quantity during last two years in Mayo Hospital. The firm admitted that due to Covid Public Sector Hospitals have more than sufficient stocks of 500ml. Even Mayo purchased lesser quantities than actual demands. Keeping in view the reduced demand the firm requested to give 10 numbers. Regarding Sr. No. 5 (D)Credibility and Certification of Manufacturer: The firm claimed that it has SOPs and required facility for water treatment plantas per the requirement. However, operation is responsibility of third party under contract and requested to give 3 numbers. Regarding Sr. No. 9 Primary reference standards; The firm claimed to have complete primary reference standards and requested to give 2 marks. Regarding Sr. No. 10 Technical Staff of Manufacturing Unit: (A) 10 Pharmacists are required in a manufacturing unit having different section like solid dosage, liquid dose, parental, topical preparations, cephalosporin, hormones etc. The firm's representative stated that M/S Gallop Water Sciences is a parental plant and 4 pharmacists are appointed who supervise the processes skillfully thus requested to give 2 marks.(B) The firm claimed to have 3 M.Phil working in plant and requested to give 2 marks. Regarding Sr. No. 11 (A) Availability of products at Major Chain pharmacies: The firm stated that Inf. RL 500ml is indicated for dehydration in children and patients are admitted in hospitals, surgery and ICU, so it is a specialized hospital item and should be exempted from this requirement. The firm requested to accept its grievances to give 54 marks and declare GEE-Sol RL 500 ml as "Responsive".

Fourthly regarding tender Bid Reference No. 19 where the firm quoted Inf. GEE-Metro 100ml against T.E. No 16 Inf. Metronidazole 500mg/100ml that has been declared "Non-Responsive" due to lesser marks in different parameters. Regarding Sr. No. 3 (A)Experience of quoted product last two year in Private sector: The firm stated that GEE-Metro has experience of private sector of advertised quantity but due to Covid and consequent problems and limitation in import the firm could not procure raw material and had lesser experience in private sector. The firm requested to consider

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

Page 17 of 19

Signature

Signature

MINUTES OF GRIEVANCES MEETING



MAYO HOSPITAL LAHORE

the unavoidable situation and give 10 marks in addition. Regarding Sr. No. 4 (A) Experience of quoted product last two year in Govt. sector: The firm admitted that GEE-Metro has no experience of public sector hospitals of advertised quantity during last two years due to Covid and consequent problems and limitation in import it could not procure raw material and did not participated in public sector tenders. However, in 2021-22 the firm claimed to supply said drug in Govt Hospitals in 2021-22. The firm requested to consider the unavoidable past situation and give 10 marks as total in this parameter. Regarding Sr. No. 5 (D) Credibility and Certification of Manufacturer: The firm claimed that it has SOPs and required facility for water treatment plant according to requirement, however operation is responsibility of third party under contract. The firm requested to give 3 marks. Regarding Sr. No. 9 Primary reference standards: The firm stated that it has complete primary reference standards and requested to give 3 marks. Regarding Sr. No. 10 Technical Staff of Manufacturing Unit: (A) 10 Pharmacists are required in a manufacturing unit having different sections like solid dosage, liquid dose, parental, topical preparations, cephalosporin, hormones etc. The firm's representative claimed that M/S Gallop Water Sciences is a parental plant and 4 pharmacists are appointed who supervise the processes skillfully thus requested to give 3 marks. (B) The firm also claimed to have 3 M.Phil personals and requested to give 3 marks. Regarding Sr. No. 11 (A) Availability of products at Major Chain pharmacies: the firm stated that Metronidazole is indicated for anaerobic infection and patients are admitted in hospitals, so it is a specialized hospital item and should be exempted from this requirement. The firm requested to accept its grievances to give 51 marks and declare GEE-Metro 100ml as "Responsive".

Decision:

Mr. Fiaz, Regional Sales Manager of M/S Gallop Water Sciences. pleaded the case before the grievances committee. The firm's representative presented the above stated grievance. The firm's representative provided Appointment Letters & Educational documents in favor of Mr. Ahmad Kamal Moosa & Mr. Nazar Abbas for which the committee decided to award 2

Office of Chairman Grievances Committee, Mayo Hospital Lahore

18-07-2024

Page 18 of 19

Signature

Signature

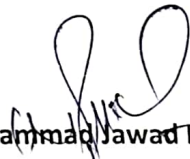
MINUTES OF GRIEVANCES MEETING

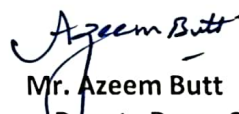
MAYO HOSPITAL LAHORE




marks in clause 10 of ordinary parameters. The firm's representative failed to provide layout plan and SOPs for Wastewater Treatment Plant required under clause 5D of ordinary parameters. The firm's representative also failed to provide necessary documents required under clause 9 of ordinary parameters. The firm provided some invoices of chain pharmacies but did not present any undertaking that its quoted product is available at retail chains as per provided record submitted in bid as required under clause 11 of ordinary parameters. The firm's representative also admitted that they don't have product experience at public institutions in the last two years as required under clause 4 of ordinary parameters. **The firm remained non-responsive due to less marks in ordinary parameters.**


The meeting ended with vote of thanks to and by the Chair.


Mr. Muhammad Jawad Bhatti
Deputy Drugs Controller
Mayo Hospital Lahore


Mr. Azeem Butt
Deputy Drugs Controller
Mayo Hospital Lahore


Dr. Sana Farooq
Senior Registrar Neurology Dept.
Mayo Hospital Lahore

Dr. Umar Nazir
Assistant Professor Plastic Surgery
Mayo Hospital Lahore (*Umar*)


Dr. Nasir Chaudhary
HoD Ophthalmology Department
Mayo Hospital Lahore

AMS(P)
upload As Per
Rules
shyam
11/8/24